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May 25, 1999

RE: DOCKET NO. 98N-1265

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20857-0003

To Whom It May Concern:

I am writing to you as a concerned and disapproving consumer. I am opposed to the current drafting of the Memorandum of Understanding as published by the FDA on January 21, 1999.

In its present form, the MOU, along with the Compounding Section 503A of the Modernization Act, severely limits the rights of consumers, pharmacists, and physicians. It should be the choice of the consumer as to the type of medical treatment he/she wants to receive, as it is the right of physicians and pharmacists to serve the public's medical needs. There should be no limitations on compounded drugs, as they are sometimes the only option for consumers. I speak from experience, as I use compounded drugs for medical needs that cannot be helped by conventional, synthetic medicines. I am seriously opposed to all restrictions implied in the MOU. The Memorandum of Understanding must be amended.

It is the job of the Food and Drug Administration to protect consumers. The MOU does not protect consumers, but rather takes away their right of choice. Compounded drugs are just as beneficial as conventional drugs and are currently used as effective treatments for a wide variety of ailments. They do not pose a threat in any way to the safety of the public; therefore, it is wrong to place restrictions on their production and availability. Again, the Memorandum of Understanding must be amended.

Thank you for your time.

Sincerely,

Denny Martin
San Diego, California

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